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Chief U.S. Dist. Judge (ret.)  
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December 30, 2024

**VIA ECF and Email****TO ALL COUNSEL OF RECORD****RE: *Johnson & Johnson Health Care Systems, Inc. v.*  
*SaveOnSP, LLC, et al., Civ. Action No.: 22-2632(JKS)(CLW)***

Counsel:

This Letter Order resolves two discovery motions filed by Defendant SaveOnSP, LLC (“Defendant” or “SaveOnSP”), which seek to compel Plaintiff Johnson & Johnson Health Care Systems, Inc. (“Plaintiff” or “JJHCS”) to 1) produce documents regarding the CAP program from its vendor TrialCard Inc., now known as Mercalis, Inc. (“TrialCard”); and 2) answer one portion of its response to Interrogatory No. 12 and to supplement another. Because the parties have made substantial progress in resolving some of the issues raised by these motions, I am addressing these motions without oral argument. As the parties are well aware of the facts, I will not detail them here.

**I. TrialCard Documents**

In April 2024, SaveOnSP moved to compel JJHCS to produce documents held by third-party vendor TrialCard. Specifically, SaveOnSP sought: (1) updated documents (July 1, 2022–November 7, 2023) from four “Original TrialCard Custodians,” and (2) documents about JJHCS’s CAP program from both the original custodians and “New TrialCard Custodians.” On May 28, 2024, I granted the motion (“May Order”), finding

JJHCS has “legal control” over the documents and that they are relevant to the CAP Program’s creation and implementation, as well as investigations into whether patients were in SaveOnSP programs. However, I directed the parties to meet and confer on the scope of the TrialCard discovery by early June 2024. While JJHCS had refreshed its production in August 2024, JJHCS has not, according to SaveOnSP, produced any documents from the New Trial-Card Custodians, has not run the requested additional CAP-related searches for the Origin program from TrialCard, and has not provided accurate hit counts of the documents identified by SaveOn’s proposed search terms. Defendant argues that Plaintiff has failed to comply with my Order by delaying production of the TrialCard documents. On this motion, SaveOnSP asks that I provide a firm date for the production.

For its part, Plaintiff insists that it has done everything reasonable to facilitate production from TrialCard. Plaintiff represents that while TrialCard has been responsive to JJHCS’s requests, TrialCard must ensure that the documents it turns over are limited to those involving JJHCS, not its other clients, and appropriately tailored to fall within the scope permitted under the Master Service Agreement. In that regard, JJHCS further represents that TrialCard has produced documents and is in the process of producing more. In the meantime, JJHCS is reviewing those documents before producing them to SaveOnSP. JJHCS assures that the ongoing process is proceeding diligently, and that intervention is not necessary. Indeed, JJHCS advised that on November 4, 2024, TrialCard provided updated hit counts, which were shared with SaveOnSP.

During the pendency of this motion, I received an email from counsel for SaveOnSP acknowledging that JJHCS has provided corrected hit counts for SaveOnSP's proposed search terms, and that the parties are continuing to negotiate regarding the search terms for this TrialCard production. The parties advised that if they are unable to reach agreement on the search terms, I will be so notified.

TrialCard's document production to SaveOnSP appears to be progressing, albeit subject to significant delays. While I recognize that obtaining documents from a third-party vendor involves multiple levels of review, more than six months have passed since I directed the parties to confer in May 2024, and production remains outstanding. Although I am not imposing a firm deadline at this time, given the parties' apparent cooperation, I strongly encourage Plaintiff to address any remaining issues expeditiously. If there are unexplained or unreasonable delays, SaveOnSP shall notify me, and I will consider imposing a strict deadline.

## **II. Best Price Rule<sup>1</sup> Interrogatories**

Defendant moves to compel Plaintiff to answer one portion of its response to Interrogatory No. 12 and to supplement another. The Interrogatories relate to an internal checklist that Defendant claims might have been a "best price" certification to the federal

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<sup>1</sup> The Best Price Rule is a federal regulatory framework mandating that drug manufacturers ensure Medicaid recipients receive the lowest available market price for prescription medications. Under this rule, manufacturers must submit quarterly reports to the government detailing various pricing data in accordance with federal guidelines. See 42 C.F.R. § 447.510(a). Drug manufacturers may exclude copay assistance from the Best Price calculation, provided they intend for that assistance to benefit patients directly.

government pursuant to Department of Health and Human Services' Proposed Amended Best Price Rule, which never went into effect.<sup>2</sup> In the May Order, I stated that I agreed with Defendant that the documents in this context may reveal Plaintiff's intent and motivation in identifying its patients who are on SaveOnSP's programs; however, I instructed Defendant to serve interrogatories on Plaintiff to discover facts surrounding the internal checklist before any document production takes place.

Pursuant to the May Order, Defendant served three interrogatories (Nos. 11-13), and specifically, Interrogatory 12 asked the following:

Describe the purpose and meaning of the Savings Program Checklists, including the meaning of the statements like those highlighted in Appendix 1; what steps, if any JJHCS took to ensure that these statements were accurate; when and why JJHCS created the Savings Program Checklists and, if applicable, stopped using them; and how the Savings Program Checklists relate to calculations or submissions of best price information pursuant to 42 C.F.R. § 447.505.

SaveOnSP's Fourth Set of Interrogatories, ¶ 12.

Plaintiff responded as follows:

The "Coupon and Free Product" checklist was an internal means of tracking whether new or modified patient assistance programs, including CarePath's co-pay assistance programs, had undergone internal compliance review before being made available to the public. Johnson & Johnson attorneys and compliance specialists generally reviewed internal drafts of the "Coupon and Free Product" checklists for accuracy and to confirm that new or modified patient assistance programs complied with Johnson & Johnson's legal obligations. In so doing, Johnson & Johnson also confirmed that its patient assistance programs complied with Johnson & Johnson's obligations under the Medicaid Drug Rebate Program. The "Coupon and Free Product" checklists were not submitted to the

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<sup>2</sup> In 2020, the Department of Health and Human Services proposed amending the Best Price Rule to require manufacturers to include copay assistance payments in Best Price calculations, unless the full benefit of those payments was passed on to the patient.

government and did not otherwise relate to Johnson & Johnson's "calculations or submissions of best price information pursuant to 42 C.F.R. § 447.505." The "Coupon and Free Product" checklists were created prior to the Time Period and continued to be used after the Time Period.

The purpose of the language in Part III, Sections 3 and 8 of the internal "Coupon and Free Product" checklist (JJHCS\_00204199) is meant to ensure these patient assistance programs, including CarePath's co-pay assistance program, operate consistently with Johnson & Johnson's compliance goals. The language in Part III, Sections 3 and 8 of JJHCS\_00204199 predate the Time Period and remained in effect after the Time Period.

JJHCS's Responses and Objections, 7-8.

Based on the content of the checklist, Defendant categorized two separate statements that employees had to certify: 1) the full value of the assistance is passed on to the consumer ("Full Value Statement");<sup>3</sup> and 2) complied with all the requirements outlined in the checklist ("Compliance Statement").<sup>4</sup> Defendant claims that the internal checklist purportedly required employees to certify that all the copay assistance funds went to patients, not to any third parties, including SaveOnSp.

Defendant contends that Plaintiff's response is wholly inadequate. Specifically, regarding the Full Value Statement, Defendant maintains that Plaintiff failed to provide

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<sup>3</sup> The Full Value Statement as printed on the checklist reads as follows:

**The full value of the assistance is passed on to the consumer.** The entire amount of the program is made available to the patient, with-out any opportunity for the retail pharmacy or any other third party (such as an insurer or PBM), to reduce the benefit amount, or take a portion of it, for its own purposes. This means the pharmacy receives no payment under the program except a bona fide service fee.

<sup>4</sup> For ease of reference, I will also use these two categories here.

a substantive response. As to the Compliance Statement, Defendant complains that Plaintiff merely stated the checklist was designed to ensure patient assistance programs operate in accordance with the company's "compliance goals," without defining those goals.

Plaintiff counters that it has adequately answered the Interrogatories. With respect to the Compliance Statement, Plaintiff explains that the checklist process "confirm[s] that its patient assistance programs complied with Johnson & Johnson's obligations under the Medicaid Drug Rebate Program," which necessarily encompasses Best Price. Defendant, in its reply brief, appears satisfied with this explanation and requests that I compel Plaintiff to amend its response to include this clarification. In the interest of efficiency, and based on Plaintiff's representation in this filing, this Order shall incorporate Plaintiff's complete response, and Plaintiff is therefore bound by that representation.

Regarding the Full Value Statement, as indicated above, Plaintiff explained the purpose of that checklist item and, more importantly, clarified that it was not created for, or otherwise connected to, the proposed amendment to the Best Price Rule. Still, Defendant contends that Plaintiff's response is inadequate because it does not explain what "full value" entails, particularly given Plaintiff's allegation in the Complaint that Defendant pilfered Plaintiff's co-pay assistance funds. Defendant therefore argues that it is entitled to understand what Plaintiff meant by those statements and how Plaintiff reconciles them with the Full Value Statement.

However, in making its argument, Defendant interprets my May Order too broadly. Contrary to its position, in both my May Order and in my comments during the

hearing, I intended Defendant to explore whether the internal checklist was changed in any way *in response* to the proposed amendment to the Best Price Rule. Indeed, in my May Order, I reasoned:

As to the Best Price Rule motion, Defendant sought documents regarding Plaintiff's "best price" certification to the federal government pursuant to Department of Health and Human Services' Best Price Rule. These documents are related to Defendant's Requests for Production Nos. 8, 70 and 79. Defendant insists that it is entitled to such documents for its mitigation defense; that is, to show that Plaintiff changed certain terms and conditions of its CarePath program and the creation of the CAP Program in response to the promulgation of the 2023 Best Price Rule, which never went into effect. [] I agree with Defendant's position that these documents may reveal Plaintiff's intent and motivation in identifying its patients who are on SaveOnSP's programs . . . .

May Order, 2. Put differently, I found that Defendant was entitled to discover whether Plaintiff modified or created its checklist as a result of the proposed rule. In my view, Plaintiff's interrogatory response adequately addresses that issue, even if it does not seem to support Defendant's position. If Defendant has additional questions, it may pursue them during depositions.

/s/ Freda L. Wolfson  
Hon. Freda L. Wolfson (ret.)  
Special Master